REMARKS

I. Status of the Claims

Claims 50-52, 55-57 and 59-62 were pending and examined in the May 25, 2010 Office Action. With this Reply, claims 50, 52, 59 and 60 are amended and claim 63 is newly added. The amendments are made without prejudice or disclaimer and provide no new matter. Support for the amendments is found at least at page 16 of the application as filed. Claims 50-52, 55-57, 59, 60, 62 and 63 are presented for reconsideration.

II. Rejection under 35 U.S.C. § 112, Second Paragraph – Indefinite

Claim 59 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for depending from a canceled claim. Withdrawal of this rejection is respectfully requested since claim 59 as amended depends from claim 50, which is not canceled.

III. Rejections under 35 U.S.C. § 102

Claims 50-52 and 55-57 are rejected under 35 U.S.C. 102(b) as being unpatentable over Motoki et al. (Biol. Pharm. Bull., 1995, 18:1487-1491) as evidenced by Elgert et al. (Journal of Leukocyte Biology, 1998, 64:275-290). The Action asserts that Motoki et al. teach (a) the administration of a mammalian metabolite to subjects that have cancer and (b) that the metabolite is immunostimulatory. Elgert et al. is asserted to teach that cancer induces immune dysfunction in a subject.

Claim 50, to which the other pending claims depend, is directed to

> A process for modulating an immune response in a mammalian subject comprising administering to said subject an effective amount of a mammalian metabolite so as to modulate or change at least one component in the immune system of said subject, wherein the mammalian metabolite is a glycolipid, and wherein the immune response is part of the pathogenesis of a disease comprising an infection or an auto-immune disorder.

Motoki et al. teach that various monoglycosylceramides have immunostimulatory and antitumor activities (Motoki et al., abstract). However, Motoki et al. do not teach or suggest modulating an immune response in a mammalian subject, where the immune response is part of the pathogenesis of an infection or an auto-immune disorder, as claimed. As such, Motoki et al. does not teach or suggest each element of the instant claims as amended, and as such does not anticipate those claims. Withdrawal of the rejection under 35 U.S.C. 102(b) is therefore respectfully requested.

IV. Rejections under 35 U.S.C. § 103

Claims 50-52, 55-57, 59-60 and 62 are rejected under 32 U.S.C. 103(a) as being unpatentable over Motoki et al. (discussed under **III.** above) as applied to claims 50 and 58, in view of Ogawa et al. (US Patent 5,861,520). The Office Action asserts that (a) both references teach the glycolipids recited in the claims, (b) Ogawa et al. establishes that glycolipids have antiviral activities, and (c) Motoki et al. establishes that the conjugate recited in the claims is immunostimulatory.

As discussed under **III.** above, Motoki et al. teach that various monoglycosylceramides have immunostimulatory and antitumor activities (Motoki et al., abstract), but does not teach or suggest modulating an immune response in a mammalian subject, where the immune response is part of the pathogenesis of an infection or an auto-immune disorder, as claimed. Also, Ogawa et al. teach the synthesis of glycolipid analogs of monoglycosylceramides, where the glucose or galactose of the natural glycolipid is replaced with various carbocyclic sugar analogs (Ogawa et al., col. 5, l. 13-30). The analogs (but not the natural compounds) inhibit glycosidase "...and have potential physiological activities, such as antiviral activity...." (Ogawa et al., col. 2, l. 28-29; see also Table I at col. 26 and Table 2 at col. 27). By virtue of this glycosidase-inhibitory activity, the analogs inhibited HIV infection and syncitia formation in cell cultures (Ogawa et al., col. 28, l. 20-42; FIGS. 1 and 2).

Neither Ogawa et al. nor Motoki et al. teach or suggest that administration of a mammalian glycolipid is useful to modulate an immune response that is part of the

pathogenesis of a disease comprising an infection or an auto-immune disorder. The Office Action asserts the contrary, stating "Ogawa et al. also establishes that it is known that glycolipids play a role as a receptor in the host side in the infection with bacteria and viruses. [Lines 55-61, column 1, in particular.] Based on this knowledge, Ogawa et al. discloses the use of glycolipids to inhibit viral infection." The cited portion of Ogawa et al. states:

> It is known that this sphingoglycolipid closely relates to receptor functions for physiologically active substances and important cell functions, such as generation, proliferation, differentiation or immune reactions, via intercellular recognition and interactions. It is also known that this sphingoglycolipid plays a role as a receptor in the host side in the infection with bacteria or viruses.

It is unclear to Applicants how the above passage would teach the skilled artisan that glycolipids could be used to inhibit or treat a viral infection. The mere fact that glycolipids may be involved in viral infection does not teach the skilled artisan that administration of such a substance will have any particular effect *per se*. The passage does not state or suggest, or even point to a reference that states or suggests that any glycolipid could have antiviral activity or could be used to inhibit or treat a viral infection. The passage merely states that sphingoglycolipids plays a role in host receptors for bacteria and virus infections. Nowhere in that passage, or anywhere else in Ogawa et al., would lead the skilled artisan to conclude that sphingoglycolipids are useful as antiviral agents.

With regard to the other physiological responses listed in the passage cited by the Examiner (Ogawa et al., col. 1, lines 55-61) (*i.e.*, "generation, proliferation, differentiation or immune reactions, via intercellular recognition and interactions"), it should be noted that those responses would not be understood to strictly relate to a normal mammal intermediary metabolite since the passage refers to sphingoglycolipids represented by the formula (b), which is denoted as having "X" linking the sugar and lipid portions of "this glycolipid" where "X represents NH, O or S". As such only one member of this group (X = O) is a naturally occurring mammalian intermediary metabolite, while X = NH or X = S are unnatural analogs of normal mammalian

intermediary metabolites. Consequently, the listed effects would be understood to belong in general to the structure (b) family but there is no particular indication which particular member (or members) are linked to each of the listed effects. Thus from a reading from this passage it would be unknown to the skilled artisan whether each of the possible variants, (NH, O or S) is able affect proliferation (for example) or if it is a particular member of the group that has been shown to affect proliferation and which one it might be. Thus, the cited passage would not direct the skilled artisan to the conclusion that the "mammalian metabolite" as recited in the instant claims have the recited physiological responses.

In light of the above, it is clear that Ogawa et al. do not teach or suggest that any glycolipid "is part of the pathogenesis of a disease comprising an infection or an auto-immune disorder" as claimed. Motoki et al. also do not teach or suggest that function for any glycolipid mammalian metabolite. Thus, the Office Action also does not point to any studies in Ogawa et al., Motoki et al. or anywhere else showing that mammalian sphingoglycolipids are useful to modulate an immune response that is part of the pathogenesis of a disease comprising an infection or an auto-immune disorder, as claimed. As such, the combination of references do not make the instant claims obvious. Withdrawal of the rejection under 35 U.S.C. 103(a) is therefore respectfully requested.

V. Doubl e Patenting Rejections

Claims 50-52, 55-57, 59-60 and 62 are provisionally rejected on the ground of obviousness-type double patenting (ODP) as being unpatentable over claims 1, 4-6, 9 and 11 of copending Application No. 10/375,906. Since this rejection is dependent on the scope of both the instant claims and the claims in the cited applications, Applicants will provide a terminal disclaimer where necessary when a proper ODP rejection is the only rejection remaining in this application.

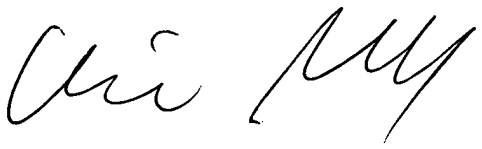
VI. Conclusion

In view of the foregoing remarks, Applicants respectfully request withdrawal of the rejections of record and passage of all claims to allowance.

Applicants authorize the United States Patent and Trademark Office to charge all fees required to maintain pendency of this application, including the extension of time and Request for Continued Examination fees, to Deposit Account No. 05-1135.

If a telephone conversation would further the prosecution of the present application, Applicants' undersigned attorney requests that he be contacted at the number provided below.

Respectfully submitted,



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